

Atty. Dkt. No. 24301
Serial No. 09/606,219
Filed: June 29, 2000

matter within the meaning of 35 U.S.C. 132 is added by the amendments and newly submitted claims.

Claims 12, 15, 16, 18, 19, 20 and 21 stand rejected under 35 U.S.C. 112, second paragraph as being indefinite. Claims 12, 13 and 14 and 10-14 stand rejected under 35 U.S.C. 102(b) as being anticipated by Bastioli et al. (U.S. Patent No. 5,462,980). Claim 15 stands rejected under 35 U.S.C. 103(a) as being obvious over Bastioli et al. in view of Nakajima et al. (U.S. Patent No. 5,098,606); claims 16, 17 and 21 stand rejected as being obvious over Bastioli et al. in view of Wittwer et al. (U.S. Patent No. 4,673,438); and claims 18-20 stand rejected as being obvious over Bastioli et al. in view of Wittwer et al. and in further view of Bastioli et al. (U.S. Patent No. 5,569,692).

With entry of the above attached amendments, Applicant respectfully submits that the claims are now in condition for allowance.

1. REJECTION OF CLAIMS 12, 15, 16, 18, 19, 20 and 21 UNDER

35 U.S.C. 112, SECOND PARAGRAPH

The Examiner has rejected claims 12, 15, 16, 18, 19, 20 and 21 under 35 U.S.C. 112, second paragraph as being indefinite for the reasons set forth below.

The phrase "strength om" in claim 19 is unclear, which renders the claim vague and indefinite. It is unclear from the claim language what is meant by the symbol, if it is trying to be specific in the way the weight was tested, or if it is just a symbol that represents the measurement of weight in general.

RESPONSE

Applicants have amended claim 19 to include om before and after the om, thus indicating that om is a symbol that represents the measurement of the weight in general. Thus, by the amendment to claim 19, Applicants have removed the basis for this rejection, rendering the rejection moot. Applicants respectfully request reconsideration and withdrawal of the rejection.

Claim 21 recites the limitation "at least two films have a different chemical composition" in a shape body consisting of a multi-layered film. There is insufficient antecedent basis for this limitation in the claim. There is no mention of film in the shape body claims.

RESPONSE

Applicants have amended claim 21 by changing the films having a different chemical composition to having at least two layers of the multi-layered film having different chemical compositions. In reading the English translation of the specification, the only way the specification makes any sense is if at least two layers of the multi-layered film have different chemical compositions. Thus, Applicants have amended claim 21 to be consistent with this

understanding. Applicants have thus provided proper antecedent basis for the limitations found in claim 21, thus rendering this rejection moot. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 12 recites the broad recitation "the limiting viscosity of the homogenized mass is at least 40 ml/g", and the claim also recites "preferably at least 50mVg and even more preferably at least 60 ml/g" which is the narrower statement of the range/limitation.

RESPONSE

Applicants have amended claim 12 to remove the narrower range contained within the claim (with the range being reintroduced as newly submitted claims 23 and 24), thus removing the basis for this rejection. Applicants respectfully request reconsideration and withdrawal of this rejection.

In the present instance, claim 15 recites the broad recitation "a weight ratio of 1: 1.5", and the claim also recites "preferably 1 : 1.2 and even more preferred 1 : 1" which is the narrower statement of the range/limitation.

RESPONSE

Applicants have amended claim 15 to remove the narrower range contained within the claim (with the range being reintroduced as newly submitted claims 25 and 26), thus removing the basis for this rejection. Applicants respectfully request reconsideration and withdrawal of this rejection.

In the present instance, claim 16 recites the broad recitation "in a weight range of 3.5% by weight to 15% by weight", and the claim also recites "preferably of 5% by weight to 8% by weight" which is the narrower statement of the range/limitation.

RESPONSE

Applicants have amended claim 16 to remove the narrower range contained within the claim (with the range being reintroduced as newly submitted claim 27), thus removing the basis for this rejection. Applicants respectfully request reconsideration and withdrawal of this rejection.

In the present instance, claim 18 recites the broad recitation "an elongation at rupture of at least 100%", and the claim also recites "preferably at least 160% and even more preferable 240%" which is the narrower statement of the

range/limitation.

RESPONSE

Applicants have amended claim 18 to remove the narrower range contained within the claim (with the range being reintroduced as newly submitted claims 28 and 29), thus removing the basis for this rejection. Applicants respectfully request reconsideration and withdrawal of this rejection.

In the present instance, claim 19 recites the broad recitation "a strength of at least 2 MPa", and the claim also recites "preferably a strength in the range of 3.5 to 8 MPa and even more preferred from 4 MPa to 6.5 MPa" which is the narrower statement of the range/limitation.

RESPONSE

Applicants have amended claim 19 to remove the narrower range contained within the claim (with the range being reintroduced as newly submitted claims 30 and 31), thus removing the basis for this rejection. Applicants respectfully request reconsideration and withdrawal of this rejection.

In the present instance, claim 20 recites the broad recitation "a thickness in the region between 0.1 and 2 mm", and the claim also recites "preferably between 0.2 to 0.6 mm" which is the narrower statement of the range/limitation.

RESPONSE

Applicants have amended claim 20 to remove the narrower range contained within the claim (with the range being reintroduced as newly submitted claim 32), thus removing the basis for this rejection. Applicants respectfully request reconsideration and withdrawal of this rejection.

Accordingly, Applicant respectfully submits that claims 12, 15, 16, 18, 19, 20 and 21 are now definite and respectfully requests reconsideration and withdrawal of the rejection of the same as being indefinite.

2. REJECTION OF CLAIMS 12, 13 AND 14 UNDER 35 U.S.C. 102(b)

Claims 1-2, 5-8 and 10-14 stand rejected under 35 U.S.C. 102(b) as being anticipated by Bastioli et al. (U.S. Patent No. 5,462,980) for the reasons set forth in the Office Action.

RESPONSE

Applicants respectfully traverse this rejection and request reconsideration and withdrawal thereof.

Applicants respectfully submit that the reference fails to anticipate the claims. The test for anticipation is whether each and every element as set forth is found, either expressly or

inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP § 2131. The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); MPEP § 2131. The elements must also be arranged as required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990).

As can be seen by the amended claims attached hereto, claim 12 is directed to a homogenised starch-containing mass, containing preferably at least 45% by weight of an amorphous starch with an amylopectine content of greater or equal to 50% by weight with respect to the weight of the starch in water-free condition, water, at least one organic softener in at least 12% by weight with respect to the weight of the water-free starch, wherein the limiting viscosity index of the homogenised mass is at least 40 ml/g.

Applicants respectfully submit that Bastioli et al. fail to teach each and every claimed element of claims 12, 13 and 14. Turning to the Declaration (1.132) of Rico Menard (attached herewith), it is abundantly clear that Bastioli et al. fail to teach a homogenized starch-containing mass, as is required by claim 12 (Dr. Menard references the subject matter of the claims in paragraph 5 of the declaration). According to Mr. Menard,

"homogenized" is a term of art that is understood as meaning a system with only one phase, independent from the number of components. This is how the limitation in claim 12 is interpreted within the art. Bastioli et al., on the other hand, disclose a material having a laminar structure of at least two different components, and therefore the product is not homogenized, as is required in the instant claims. The laminar structure of the materials formed by Bastioli et al. is clearly shown in Figures 1, 3-5 and 8-11 of the patent. The figures are of scanning electron microscope photographs showing that the compositions of Bastioli et al. are not homogenized.

Further, as is stated in column 2, lines 53-57 of the reference, "when films produced with the use of amylose starches or conventional starches are observed by SEM (scanning electron microscope), on the other hand, they show a microstructure formed by microglobules constituted by an interpenetrated synthetic polymer and starch structure." (Emphasis added). Thus, this is further evidence that no homogenized mass is obtained, but rather a separation of the starch and synthetic polymeric compounds is observed.

The products of the present claims, on the other hand, are required to be homogenized masses. Attached to Mr. Menard's declaration is a scanning electron microscope image of a cross-

section through a broken part of foil made from a composition according to claim 12. It can be seen that the broken part consists of a homogenous material. Note that the white stripes at the edges of the part are tears which were generated during breaking of the part due to tension and the black spots are microscopically small inclusions of air. Also, the very few white spots are contaminations of the probe. However, it is very evident that the material is homogenous in nature.

A still further point regarding the Bastioli et al. reference is the inclusion of a thermoplastic synthetic polymer. According to Mr. Menard, the addition of such polymers will influence the limiting viscosity index of the entire mass so that it falls out of the claimed range.

Thus, Applicants respectfully submit that Bastioli et al. fail to anticipate the claims because the reference does not teach a homogenized starch-containing mass as is required by the claims. Therefore, Applicants respectfully request reconsideration and withdrawal of this rejection.

3. REJECTION OF CLAIM 15 UNDER 35 U.S.C. 103(a)

Claim 15 stands rejected under 35 U.S.C. 103(a) as being obvious over the Bastioli et al. patent (U.S. Patent No. 5,462,980) in view of the Nakajima et al. patent (U.S. Patent No. 5,098,606)

for the reasons set forth in the Office Action.

RESPONSE

The references of record, Bastioli et al. and Nakajima et al., do not teach or suggest applicant's inventive subject matter as a whole, as recited in the amended claims. Further, there is no teaching or suggestion in this references which would lead the ordinary skilled artisan to modify the references to derive the subject matter as defined in the amended claims.

The U.S. Supreme Court in *Graham v. John Deere Co.*, 148 U.S.P.Q. 459 (1966) held that non-obviousness was determined under § 103 by (1) determining the scope and content of the prior art; (2) ascertaining the differences between the prior art and the claims at issue; (3) resolving the level of ordinary skill in the art; and, (4) inquiring as to any objective evidence of nonobviousness.

A. The present inventive subject matter

Claim 15 depends from claim 13, which further depends from claim 12 and adds the further limitation of the mass containing glycerine monostearate and lecithin in a weight ratio of 1:1.5. Since claim 15 depends from claim 13 (and therefore from claim 12),

it necessarily contains all of the limitations found in claim 12 and thus if claim 12 is not obvious over the references, then neither is claim 15.

B. The prior art and the differences therein

As is discussed above, while the present inventive subject matter is directed to a homogenized starch-containing mass, Applicants respectfully submit that the Bastioli et al. patent discloses a polymeric composition comprising a starchy material component comprising at least 78% by weight of amylopectin, and a synthetic thermoplastic polymeric component and urea. Bastioli et al. found that the thermoplastic polymeric compositions formed laminar structures from the plurality of laminar microphases of the synthetic polymer alternating with the starchy phases. The aim of the Bastioli et al. patent was to provide films or sheets having improved liquid- and gas-barrier and mechanical properties in comparison with films produced from conventional starches with high amylose content. The laminar structures were found to improve the liquid- and gas-barrier structures. In other words, Bastioli et al. purposely did not provide homogenized masses, but rather a material having laminar structures of at least two different components in order to improve the barrier structures.

Further, Bastioli et al. do not disclose or suggest a material

which can be used for the formation of soft capsules. In general, materials that are not homogenous are not reliably reproducible with respect to the properties because the differences in homogeneity cannot be exactly reproduced. Also, the polymeric compounds used within the Bastioli et al. formulations will not dissolve under conditions occurring in the human stomach and/or intestinal tract. Thus, there would be no reason or motivation to try to alter the Bastioli et al. compounds to try to achieve the presently claimed subject matter in independent claim 12 and dependent claim 15.

Turning now to the Nakajima et al. patent, this patent does not deal with soft capsules, much less homogenized starch-containing masses. In addition, Applicants note that Nakajima et al., at column 3, lines 27-28, do not refer to glycerine monostearate but to POE glycerine monostearate, which is polyoxyethylene glycerine monostearate. This is not the lubricant referred to in claims 13 and 15 of the present application.

Thus Applicants respectfully submit that there is no motivation or teaching in either reference to combine them in an attempt to achieve the present inventive subject matter. Assuming *arguendo* that the references were combined, Applicants respectfully submit that the combination would still be lacking the elements of the present claims. In particular, the combination would not be a

homogenized starch-containing mass with the properties listed in claims 12 and 15.

Accordingly, Applicant respectfully submits that the present inventive subject matter as claimed is not obvious over the Bastioli et al. and Nakajima et al. patents, as there is no teaching or suggestion in the references to modify them, and the combination thereof would not achieve the presently claimed products. Applicants respectfully request reconsideration and withdrawal of this rejection.

4. REJECTION OF CLAIM 16, 17 AND 21 UNDER 35 U.S.C. 103(a)

Claims 16, 17 and 21 stand rejected under 35 U.S.C. 103(a) as being obvious over the Bastioli et al. patent (U.S. Patent No. 5,462,980) in view of the Wittwer et al. patent (U.S. Patent No. 4,673,438) for the reasons set forth in the Office Action.

RESPONSE

The references of record, Bastioli et al. and Wittwer et al., do not teach or suggest applicant's inventive subject matter as a whole, as recited in the amended claims. Further, there is no teaching or suggestion in this references which would lead the ordinary skilled artisan to modify the references to derive the subject matter as defined in the amended claims.

The U.S. Supreme Court in *Graham v. John Deere Co.*, 148 U.S.P.Q. 459 (1966) held that non-obviousness was determined under § 103 by (1) determining the scope and content of the prior art; (2) ascertaining the differences between the prior art and the claims at issue; (3) resolving the level of ordinary skill in the art; and, (4) inquiring as to any objective evidence of nonobviousness.

A. The present inventive subject matter

Claims 16, 17 and 21 depend from claim 12 (claim 21 depends from claim 17) and add further limitations including the mass additionally containing an aggregate in a weight range of 3.5% by weight to 15% by weight with respect to the total weight of the mass, wherein the aggregate is selected from the group consisting of carbonates and/or hydrogen carbonates of alkali and/or earth alkali ions, preferably calcium carbonate, amylases, further decomposing agents, colourings, preservatives, anti-oxidants, physically and/or chemically modified biopolymers and vegetable polypeptides. Since claims 16, 17 and 21 depends from claim 12, they necessarily contains all of the limitations found in claim 12 and thus if claim 12 is not obvious over the references, then neither are claims 16, 17 and 21.

B. The prior art and the differences therein

As is discussed above, while the present inventive subject matter is directed to a homogenized starch-containing mass and a soft capsule made therefrom, Applicants respectfully submit that the Bastioli et al. patent discloses a polymeric composition comprising a starchy material component comprising at least 78% by weight of amylopectin, and a synthetic thermoplastic polymeric component and urea. Bastioli et al. found that the thermoplastic polymeric compositions formed laminar structures from the plurality of laminar microphases of the synthetic polymer alternating with the starchy phases. The aim of the Bastioli et al. patent was to provide films or sheets having improved liquid- and gas-barrier and mechanical properties in comparison with films produced from conventional starches with high amylose content. The laminar structures were found to improve the liquid- and gas-barrier structures. In other words, Bastioli et al. purposely did not provide homogenized masses, but rather a material having laminar structures of at least two different components in order to improve the barrier structures.

Further, Bastioli et al. do not disclose or suggest a material which can be used for the formation of soft capsules. In general, materials that are not homogenous are not reliably reproducible with respect to the properties because the differences in

homogeniety cannot be exactly reproduced. Also, the polymeric compounds used within the Bastioli et al. formulations will not dissolve under conditions occurring in the human stomach and/or intestinal tract. Thus, there would be no reason or motivation to try to alter the Bastioli et al. compounds to try to achieve the presently claimed subject matter in claims 12 the dependent claims under rejection here.

Turning now to the Wittwer et al. patent, this patent does not deal with soft capsules, much less homogenized starch-containing masses. In fact, Applicants respectfully submit that Wittwer et al. teach the manufacturing of hard capsules by an injection molding process. Because hard capsules are being made in the injection molding process, there is no need for forming highly elastic "endless" tapes with sufficient strength, the capability of being weldable, or the capability of forming stable seams by penetration of the molecules into each other.

In addition, the manufacturing parameters of Wittwer et al. are too harsh to obtain a product in accordance with the present claims. The instant invention is claimed as a homogenized mass having a limiting viscosity index of at least 40 ml/g. This is obtained by a very controlled process, as explained in the application. The process is carefully kept under a temperature of 160°C and the kneading energy of the material does not exceed 0.3

kWh/kg. If the working conditions are too harsh, then the starch molecules will become greatly broken, thus leading to a mass with properties that are not in accordance with the claims.

The conditions of the Wittwer et al. process include temperatures up to 240°C and high pressures. These conditions are not suitable for obtaining the desired products of the present claims. Further, Wittwer et al. do not teach lowering the temperature and pressures in an attempt to achieve the present claims. This is because Wittwer et al. are only concerned with obtaining a material that can be injection-molded into hard capsules, not homogenized starch-containing masses of the present invention.

Thus, Applicants respectfully submit that there is no motivation or teaching in either reference to combine them in an attempt to achieve the present inventive subject matter. Assuming *arguendo* that the references were combined, Applicants respectfully submit that the combination would still be lacking the elements of the present claims. In particular, the combination would not be a homogenized starch-containing mass with the properties listed in the rejected claims.

Accordingly, Applicant respectfully submits that the present inventive subject matter as claimed is not obvious over the Bastioli et al. and Wittwer et al. patents, as there is no teaching

or suggestion in the references to modify them, and the combination thereof would not achieve the presently claimed products. Applicants respectfully request reconsideration and withdrawal of this rejection.

5. REJECTION OF CLAIM 18-20 UNDER 35 U.S.C. 103(a)

Claims 18-20 stand rejected under 35 U.S.C. 103(a) as being obvious over the Bastioli et al. patent (U.S. Patent No. 5,462,980) in view of the Wittwer et al. patent (U.S. Patent No. 4,673,438) as applied to claim 16, 17 and 21 above, and further in view of Bastioli et al. (U.S. Patent No. 5,569,692) for the reasons set forth in the Office Action.

RESPONSE

The references of record, the two Bastioli et al. patents and the Wittwer et al. patent, do not teach or suggest applicant's inventive subject matter as a whole, as recited in the amended claims. Further, there is no teaching or suggestion in this references which would lead the ordinary skilled artisan to modify the references to derive the subject matter as defined in the amended claims.

The U.S. Supreme Court in *Graham v. John Deere Co.*, 148

U.S.P.Q. 459 (1966) held that non-obviousness was determined under § 103 by (1) determining the scope and content of the prior art; (2) ascertaining the differences between the prior art and the claims at issue; (3) resolving the level of ordinary skill in the art; and, (4) inquiring as to any objective evidence of nonobviousness.

A. The present inventive subject matter

Claims 18-20 depend from claim 12 (claim 21 depends from claim 17) and add further physical limitations to the soft capsule body. Since claims 18-20 depend from claim 17 and therefore from claim 12, they necessarily contains all of the limitations found in claim 12 and thus if claim 12 is not obvious over the references, then neither are claims 18-20.

B. The prior art and the differences therein

As is discussed above with respect to the previous 103(a) rejections, while the present inventive subject matter is directed to a homogenized starch-containing mass and a soft capsule made therefrom, Applicants respectfully submit that the Bastioli et al. ('980) patent discloses a polymeric composition comprising a starchy material component comprising at least 78% by weight of amylopectin, and a synthetic thermoplastic polymeric component and

urea. Bastioli et al. found that the thermoplastic polymeric compositions formed laminar structures from the plurality of laminar microphases of the synthetic polymer alternating with the starchy phases. The aim of the Bastioli et al. ('980) patent was to provide films or sheets having improved liquid- and gas-barrier and mechanical properties in comparison with films produced from conventional starches with high amylose content. The laminar structures were found to improve the liquid- and gas-barrier structures. In other words, Bastioli et al. purposely did not provide homogenized masses, but rather a material having laminar structures of at least two different components in order to improve the barrier structures.

Further, Bastioli et al. do not disclose or suggest a material which can be used for the formation of soft capsules. In general, materials that are not homogenous are not reliably reproducible with respect to the properties because the differences in homogeneity cannot be exactly reproduced. Also, the polymeric compounds used within the Bastioli et al. formulations ('980 patent) will not dissolve under conditions occurring in the human stomach and/or intestinal tract. Thus, there would be no reason or motivation to try to alter the Bastioli et al. compounds to try to achieve the presently claimed subject matter in claims 12 the dependent claims under rejection here.

In addition, as was also stated above with respect to the Wittwer et al. patent, this patent does not deal with soft capsules, much less homogenized starch-containing masses. In fact, Applicants respectfully submit that Wittwer et al. teach the manufacturing of hard capsules by an injection molding process. Because hard capsules are being made in the injection molding process, there is no need for forming highly elastic "endless" tapes with sufficient strength, the capability of being weldable, or the capability of forming stable seams by penetration of the molecules into each other.

In addition, the manufacturing parameters of Wittwer et al. are too harsh to obtain a product in accordance with the present claims. The instant invention is claimed as a homogenized mass having a limiting viscosity index of at least 40 ml/g. This is obtained by a very controlled process, as explained in the application. The process is carefully kept under a temperature of 160°C and the kneading energy of the material does not exceed 0.3 kWh/kg. If the working conditions are too harsh, then the starch molecules will become greatly broken, thus leading to a mass with properties that are not in accordance with the claims.

The conditions of the Wittwer et al. process include temperatures up to 240°C and high pressures. These conditions are not suitable for obtaining the desired products of the present

claims. Further, Wittwer et al. do not teach lowering the temperature and pressures in an attempt to achieve the present claims. This is because Wittwer et al. are only concerned with obtaining a material that can be injection-molded into hard capsules, not homogenized starch-containing masses of the present invention. Thus, there is no motivation to modify the Wittwer et al. patent.

Turning now to the second Bastioli et al. patent ('692), Applicants again respectfully submit that the patent does not disclose or teach a homogenized starch material. Instead, the '692 patent teaches the use of destructured starch which can be mixed with a thermoplastic polymer in order to obtain biodegradable plastics. A destructured starch is one in which the molecular structure has become disorganized. In other words, the large starch molecules have been broken into smaller molecules. As is argued above, this is contrary to the desired result in the present claims, and as such the '692 patent fails to teach or render obvious the physical characteristics of the present claims. Nor is there any motivation to modify the teachings of the '692 patent because, in column 1, Bastioli et al. state that the destructured nature of the starches in the patent are not suitable for filming processes. Thus, there would be no motivation to attempt to use the '692 patent to achieve the presently claimed inventive subject

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matter.

Accordingly, Applicant respectfully submits that the present inventive subject matter as claimed is not obvious over the combination of references, as there is no teaching or suggestion in any of the references to modify them, and the combination thereof would not achieve the presently claimed products. Applicants respectfully request reconsideration and withdrawal of this rejection.


CONCLUSION

In view of the foregoing, applicant respectfully requests the Examiner to reconsider and withdraw the rejection of the claims and to allow all of the claims pending in this application.

If the Examiner has any questions or wishes to discuss this matter, the Examiner is welcomed to telephone the undersigned attorney.

Respectfully submitted,
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